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Dockets Management Branch (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, Room 1061,
Rockville, MD 20852

Dear Sir or Madam,

Draft Compliance Policy Guide - Docket 99D–2638
"Use of Medicated Feeds for Minor Species."

I am a Professor of Veterinary Clinical Pharmacology at the University of Florida and the Southern Regional Drug Coordinator for NRSP-7 Minor Use Animal Drug Program. I believe the concept of this draft Compliance Policy Guide to allow extralabel use of drugs in minor species feed is admirable but really is just playing catch-up on the down side to the AMDUCA prohibition on extralabel use of drugs in feed. Even before the final AMDUCA regulations were promulgated in 1996 the Minor Species Industries [especially aquaculture and gamebirds] were clearly going to be disadvantaged and could not get any promise of relief. This draft finally does that but may, in providing immediate relief, cause long-term harm by discouraging any movement towards getting new FDA drug approvals.

It seems to this writer that, if extralabel use of drugs in feed is to be allowed for minor species, that it should be both time limited and tied to the producers, pharmaceutical companies and feed millers having to gather data for a full drug approval. In the draft, the only trace of such an obligation is the requirement to report adverse events. There is no data being collected prospectively for efficacy or target animal safety [recording side-effects is not sufficient under current FDA requirements].

It has become painfully clear to me that the proposed guidance, as proposed, will act as a disincentive to new drug approvals in minor species. I say that because I have been involved in drug approval trials being conducted by members of the Gamebird Industry and have seen their enthusiasm for gaining drug approvals for their industry diminish with publication of

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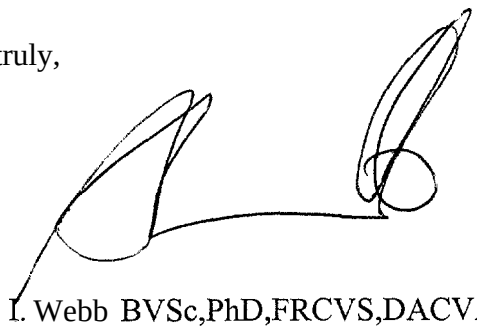
this draft. I have also been negotiating with pharmaceutical firms about embarking on clinical trials for minor species drugs and have been told that this will no longer be a priority.

AMDUCA and ADAA both set priority on adequate drugs approvals in minor species but this guidance version will work contrary to this. It is well intended but needs rethinking.

Yours truly,



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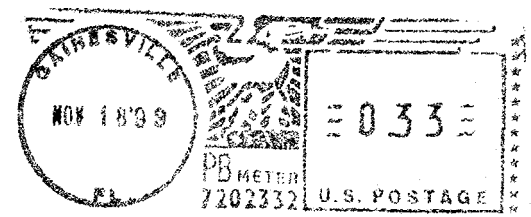

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